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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/472,688	12/27/99	SHIMKETS PH.D R	15966-534C-C

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EXAMINER	
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ART UNIT	PAPER NUMBER
1631	8

DATE MAILED: 03/22/01

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/472,688	Applicant(s) SHIMKETS PH.D ET AL.	
	Examiner Marjorie A. Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears n th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Election/R strictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to an isolated polynucleotide with polymorphic sequences, classified in class 536, subclass 23.1.

II. Claims 10-11, drawn to a polynucleotide wherein a polymorphic site is one other than those listed in Table 1, column 5, classified in class 536, subclass 23.1.

III. Claims 12-13, drawn to a polynucleotide wherein a polymorphic site is one listed in Table 1, column 6, classified in class 536, subclass 23.1.

IV. Claims 14-18, drawn to isolated allele-specific oligonucleotides with specific hybridization properties, classified in class 536, subclass 23.1.

V. Claims19-22, drawn to a method of detecting a polymorphic site, classified in class 435, subclass 6.

VI. Claim 23, drawn to a method of detecting a sequence polymorphism, classified in class 435, subclass 6.

VII. Claims 24-28, drawn to a method of determining relatedness of two nucleic acids, classified in class 435, subclass 6.

VIII. Claims 29-31, drawn to an isolated polypeptide comprising a polymorphic site, classified in class 530, subclass 324.

IX. Claims 32-34, drawn to an antibody, classified in class 530, subclass 387.9.

X. Claim 35, drawn to a method of detecting a polypeptide by antibody binding, classified in class 435, subclass 7.1.

XI. Claims 36-37 and 40, drawn to methods of treatment using a polynucleotide, classified in class 514, subclass 44.

XII. Claim 38, drawn to a method of treatment using a polypeptide, classified in class 514, subclass 12.

XIII. Claim 39, drawn to a method of treatment using an antibody, classified in class 424, subclass 139.1.

XIV. Claims 41-44, drawn to an oligonucleotide array, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I-VII, XI and XIV are separate and distinct from Groups VIII and XII because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups I-VII, XI and XIV, the critical feature is a polynucleotide whereas for Groups VIII and XII, the critical feature is a polypeptide. It is acknowledged that various processing steps may cause a polypeptide of Group VIII (for example) to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups V versus Groups VII and XII supports the undue search burden if both polynucleotides and polypeptides were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus

significantly adding to the search burden if searched together, as compared to being searched separately. Also, it is pointed out that although processing may connect two groups, such a connection does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I-VII, XI and XIV are not related to any of Inventions IX-X and XIII. Groups IX, X, and XIII are drawn to antibodies while Groups I-VII, XI and XIV are drawn to polynucleotides. These are differing biochemical entities having differing biochemical properties, structures and effects, therefore the Groups are not related.

Groups VIII and XII, drawn to polypeptides, are separate and distinct from Groups IX, X, and XIII, drawn to antibodies, as polypeptides and antibodies are drawn to different chemical entities. While the Groups are related in that the antibodies of Group IX may bind to the polypeptides of Group VIII, antibodies are known in the art to be different and distinct from other polypeptides, with unique structures and properties. As antibodies and polypeptides are different chemically and structurally, each of Groups VIII and XII are separate and distinct from each of Groups IX, X and XIII.

Inventions I-IV are separate and distinct. The groups are related in that they all recite polynucleotides; however, each group recites polynucleotides with different structures or hydridization characteristics. Each sequence is a unique structure; the different limitations of each Group (e.g. different polymorphisms or hybridization

characteristics) results in a distinct "set" of structures with characteristics different from the "sets" of the other Groups, therefore Groups I-IV are distinct.

Inventions I-IV are related to Inventions V-VII and XI as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the products of Groups I-IV can be used in any of the methods of Groups V-VII and XI, therefore each of Groups I-VI is separate and distinct from each of Groups V-VII and XI.

Inventions I-IV are separate and distinct from Group XIV. Although all of the Groups are related in that they recite polynucleotides, each of Groups I-IV is directed to a single polynucleotide whereas Group XIV is directed to an array. An array comprises a combination of elements; in this case, of oligonucleotides, and as such, would be expected to have different characteristics and properties and to give different results in methods of use than would a single polypeptide. For these reasons, each of Groups I-IV is separate and distinct from Group XIV.

Invention VIII is related to Invention XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides

of Group VIII can be used in methods of making antibodies, running ELISA's, binding assays, etc.

Invention IX is related to Inventions X and XIII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group IX may be used in either of the methods of Groups X or XIII.

Because these inventions are distinct for the reasons given above and the search required for Groups II-XIV is not required for Group I, the search for Groups III-XIV is not required for Group II, the search for Groups IV-XIV is not required for Group III, the search for Groups V-XIV is not required for Group IV, and the search for Groups I-VII and IX-XIV is not required for Group VIII, restriction for examination purposes as indicated is proper. Also, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, therefore restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers and multiple polymorphisms. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. Further, each polymorphism results in a different and distinct

sequence. Each sequence is considered a separate product, therefore a further restriction is applied to each Group. The Applicants must further elect one SEQ ID Number AND one polymorphism for examination in the elected Group detailed above (See MPEP 803.04).

MPEP 803.04 states:
Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Due to the complexity of the claims, the increase in the size of sequence databases, and the burden on the Office in searching sequences, it is now considered an undue burden to search and examine more than a single sequence, therefore requirements of 37 CFR 1.141 et seq are NOT waived, and applicant is required to elect a single sequence. Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number and polymorphism to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524.

Marjorie A. Moran
March 15, 2001.

MARY K. ZEMAN
PATENT EXAMINER
AU 1631